

Application No. 10/663,226
Amendment Dated September 15, 2008
Reply to Final Rejection of July 10, 2008

AMENDMENTS TO THE CLAIMS

This listing of claims will replace all prior versions, and listings, of claims in the application:

Listing of Claims:

Claim 1 (withdrawn) A medical device for treating a wound, comprising:

- (a) sealing means for preventing external substances from entering the wound by contacting the skin around the wound; and
- (b) gap-filling means carried by the sealing means and adapted to contact the skin around about the wound and sealingly fill gaps between the skin around the wound and the sealing means in a substantially air-tight manner when the gap-filling means is placed between the sealing means and skin.

Claim 2 (withdrawn) The medical device of claim 1, wherein the gap-filling means is substantially free of memory, whereby, when it is changed from its original shape and molded into gaps between the sealing means and skin to have a new shape, it will retain the new shape and not return to its original shape.

Claim 3 (withdrawn) The medical device of claim 1, wherein a removable cover sheet is provided, carried by the sealing means and sandwiching the gap-filling means between the sealing means and the cover sheet.

Claim 4 (withdrawn) The medical device of claim 3, wherein the cover sheet comprises a release liner.

Claim 5 (withdrawn) The medical device of claim 2, wherein an adhesive is provided, in addition to said gap-filling means, for adhering the sealing means to the skin.

Claim 6 (withdrawn) The medical device of claim 5, wherein a removable cover sheet is provided, carried by the sealing means and sandwiching the gap-filling means between the sealing means and the cover sheet, wherein the cover sheet comprises a release liner, and wherein the adhesive releaseably secures the release liner to the sealing means.

Claim 7 (withdrawn) The medical device of any one of claims 1-2, including suction means in communication with the sealing means, for providing a suction to the wound, to promote wound drainage.

Claim 8 (withdrawn) A medical device for treating a wound by promoting wound drainage comprising:

- (a) an enclosure for placement over the wound and engaging the surface of skin around the wound, the enclosure being substantially non-protruding away from the skin surface around the wound;
- (b) the enclosure including an openable and reclosable cover means for access to the wound;
- (c) with the cover means being substantially air-tight when closed; and
- (d) suction means communicating with said enclosure, for applying suction to the wound.

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Claim 9 (withdrawn) The medical device of claim 8, wherein the suction means comprises means for applying continuous suction to the wound and means for varying the level of suction applied to the wound.

Claim 10 (withdrawn) The medical device of claim 8, wherein the enclosure is substantially flexibly conformable to the surface around the wound.

Claim 11 (withdrawn) The medical device of claim 8, wherein the enclosure includes an opening that has a peripheral zone adapted to be applied to the skin surface around the wound, leaving an enclosure area inside the peripheral zone of a predetermined size, greater than the area of the wound to which the enclosure is to be applied.

Claim 12 (withdrawn) The medical device of claim 8, wherein the enclosure comprises a flexible thermoplastic film.

Claim 13 (withdrawn) The medical device of claim 8, wherein the enclosure includes a flexible extending means, wherein the volume beneath the enclosure can be reduced when suction is applied by the suction means and the extending means collapses close to the skin in response to suction applied by the suction means.

Claim 14 (withdrawn) The medical device of claim 13, wherein the extending means is bellows-like.

Claim 15 (withdrawn) The medical device of claim 8, wherein the cover means includes at least one connectable and disconnectable peripheral portion of said enclosure.

Claim 16 (withdrawn) The medical device of claim 15, wherein said cover means is adhesively connectable and disconnectable from the rest of said enclosure.

Claim 17 (withdrawn) The medical device of claim 15, wherein said cover means is connectable and disconnectable from the rest of said enclosure by means of a mechanical interlock.

Claim 18 (withdrawn) The medical device of claim 8, wherein the cover means is both adhesively disconnectible and mechanically disconnectible from the rest of said enclosure.

Claim 19 (withdrawn) The medical device of claim 8, including gap-filling means carried by the enclosure for engaging the skin around the wound, for facilitating an airtight relationship between the enclosure and skin disposed around the wound.

Claim 20 (withdrawn) The medical device of claim 8, including removable semi-rigid frame means carried by said enclosure, for facilitating shape-retention of said enclosure until the enclosure is applied to skin disposed about the wound.

Claim 21 (withdrawn) The medical device of claim 20, wherein said frame means is connected to said enclosure by pre-formed perforation means in said enclosure.

Claim 22 (withdrawn) The medical device of claim 13, wherein the extending means connects the cover means to the portion of the enclosure that engages the surface of the skin around a wound, whereby the cover means can be opened and closed when the cover means is moved away from the surface of the wound.

Claim 23 (currently amended): A medical device for treating a wound by of a patient, the wound having at least one axis extending generally parallel to the skin of the patient contiguous with the wound, said device being arranged for encouraging by controlling the direction of wound contraction of the wound along said axis, comprising:

- (a) a source of suction means arranged for applying continuous suction to the wound to facilitate continuous contraction of the wound;
- (b) an enclosure coupled to said source of suction and arranged for maintaining continuous suction on the wound by engaging the skin of the patient around the wound;
- (c) an anisotropic wound packing arranged for placement in the wound, said wound packing having at least one predetermined direction of being arranged for preferential contraction along said axis in response to the application of suction to the wound.

Claim 24 (previously presented) The medical device of claim 23, wherein the packing comprises gauze.

Claim 25 (previously presented) The medical device of claim 24, wherein the packing comprises at least one generally cylindrical gauze roll having a generally longitudinal axis and radial axes, the longitudinal axis of the roll facing outwardly from the wound and the radial axes of the roll facing sides of the wound.

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Claim 26 (previously presented) The medical device of claim 25, wherein the packing comprises a plurality of said cylindrical gauze rolls, to be disposed with their respective longitudinal axes generally parallel to each other in the wound.

Claim 27 (previously presented) The medical device of claim 24, wherein said packing comprises at least one generally spirally wound gauze roll.

Claim 28 (previously presented) The medical device of claim 23, wherein said suction means comprises a flexible bulb adapted for manual compression, an inlet conduit connecting the bulb to the enclosure, and an outlet conduit connecting the bulb to discharge.

Claim 29 (previously presented) The medical device of claim 28, further comprising a spring element inside the bulb for providing resistance to rapid decay of suction in the bulb.

Claim 30 (withdrawn) A medical device for treating a wound by promoting wound drainage, comprising:

- (a) suction means for applying continuous suction to the wound;
- (b) sealing means for maintaining suction on the wound by engaging the skin around the wound;
- (c) including leak detection means operationally disposed between the suction means and the sealing means.

Claim 31 (withdrawn) The medical device of claim 30, wherein the leak detection means is of the bubble detector type, having a liquid in a closed container, with the suction means
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connected to the container above a liquid level in the container and a connection from below the liquid level in the container to the sealing means, whereby a leak in the system will allow visible bubbles of airflow through the liquid in the container.

Claim 32 (withdrawn) The medical device of claim 30, wherein a discharge container for liquid suctioned from the sealing means is operationally disposed between the sealing means and leak detection means.

Claim 33 (withdrawn) The medical device of claim 7, wherein said suction means is a manual suction means.

Claim 34 (canceled)

Claim 35 (withdrawn) The medical device of claim 8, wherein said suction means comprises first regulator means for applying a constant first level of suction or pressure and at least an additional second regulator means for periodically applying a second level of suction or pressure, to said enclosure.

Claim 36 (withdrawn) The medical device of claim 35, including check valve means between said first regulator means and said enclosure and between said second regulator means and said enclosure.

Claim 37 (withdrawn) The medical device of claim 9, wherein the enclosure is substantially flexibly conformable to the surface around the wound and is substantially non-protruding away from the skin surface around the wound when applied to the surface around the

wound, wherein the enclosure includes an opening that has a peripheral zone adapted to applied to the skin surface around the wound, leaving an enclosure area inside the peripheral zone of a predetermined size, greater than the area of the wound to which the enclosure is to be applied, wherein the enclosure comprises a flexible thermoplastic film, wherein the enclosure includes a flexible bellows-like means, wherein the volume beneath the enclosure can be reduced when suction is applied by the suction means and the bellows-like means folds close to the skin in response to suction applied by the suction means, wherein the cover means includes at least one connectable and disconnectable peripheral portion of said enclosure, including gap-filling means carried by the enclosure for engaging the skin around the wound, for facilitating an air-tight relationship between the enclosure and skin disposed around the wound, wherein the enclosure comprises a sealing means, wherein the gap-filling means is substantially free of memory, whereby, when it is changed from its original shape and molded into gaps between the sealing means and skin to have a new shape, it will retain the new shape and not return to its original shape, wherein a removable cover sheet is provided, carried by the sealing means and sandwiching the gap-filling means between the sealing means and the cover sheet, wherein the cover sheet comprises a release liner, wherein an adhesive is provided, in addition to said gap-filling means, for sealing the sealing means to the skin, including removable semi-rigid frame means carried by said enclosure, for facilitating shape-retention of said enclosure until the enclosure is applied to skin disposed about the wound, wherein said frame means is connected to said enclosure by pre-formed perforation means in said enclosure, including wound packing means, for placement into the wound, for absorbing liquids from the wound to prevent substantial pooling of liquids in the wound, said wound packing means being of the anisotropic

type and having at least one predetermined direction of contraction in response to said suction, wherein the packing means comprises gauze, wherein the packing means comprises at least one generally cylindrical gauze roll configuration having a generally longitudinal axis and radial axes, to be disposed in the wound with it's longitudinal axis facing outside the wound and it's radial axes facing sides of the wound, including leak detection means operationally disposed between the suction means and the sealing means, and wherein the leak detection means is of the bubble detector type, having a liquid in a closed container, with the suction means connected to the container above a liquid level in the container and a connection from below the liquid level in the container to the sealing means, whereby a leak in the system will allow visible bubbles of airflow through the liquid in the container.

Claim 38 (withdrawn) The method of detecting a leak in a wound enclosure apparatus comprising the steps of:

- (a) connecting a suction means to the wound enclosure apparatus; and
- (b) connecting a flow indicating means in communication with the suction means, to determine by the flow indicated if a leak is present.

Claim 39 (currently amended): A method of controlling the direction of contraction of a wound of a patient, said wound having at least one axis extending generally parallel to the skin of the patient contiguous with said wound, said method comprising the steps of:

- (a) placing an anisotropic wound packing in [[a]] said wound in a predetermined orientation that preferentially allows a controlled strain to be imposed on the wound tissue ~~in a medically preferred along said axis direction~~;
- (b) sealing the said wound with the said packing therein to produce an enclosed space contiguous with said wound; and
- (c) applying suction to the said enclosed space and said wound and maintaining suction therein, whereupon contraction of said wound along said axis is encouraged.

Claim 40 (withdrawn) The medical device of claim 1, wherein the enclosure includes an openable and reclosable cover means for access to the wound.

Claim 41 (withdrawn) A method for treating a wound comprising: (a) applying a sealing means to the wound to prevent external substances from entering the wound by contacting the skin around the wound; and (b) providing a gap-filling means carried by the sealing means and contacting the skin about the wound with the gap-filling means and sealingly filling gaps between the skin around the wound and the sealing means in a substantially air-tight manner with the gap-filling means placed between the sealing means and the skin.

Claim 42 (withdrawn) The medical device of claim 8, wherein said suction means comprises a computer controlled device capable of providing alternating and variable pressures and suction based upon an algorithm.